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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/110,720 07/07/98 BILLING-MEDEL

P 6130.US.P1

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HM12/0525

EXAMINER

ZITOMER, S

ART UNIT

PAPER NUMBER

1634

DATE MAILED:

05/25/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/110,720**

Applicant(s)  
**BILLING-MEDEL et al.**

Examiner  
**Stephanie Zitomer**

Group Art Unit  
**1634**



☒ Responsive to communication(s) filed on Mar 5, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-44 is/are pending in the application.

Of the above, claim(s) 1-10, 15-32, 34-37, and 40-44 is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 11-14, 33, 38, and 39 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 7

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## DETAILED ACTION

### Application status

1. Receipt of the election with traverse of Invention II, claims 11-14, 33, 38 and 39, drawn to nucleic acids, filed March 5, 1999 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P. § 818.03(a)). Claims 1-10, 15-32, 34-37 and 40-44 have been withdrawn from prosecution. Please note that claim 34, drawn to a composition comprising a polypeptide, was inadvertently included with the nucleic acids group. This claim clearly belongs in the polypeptide group, Invention IV, and it has been placed there. Any inconvenience to applicant due to this change is regretted.

### Informalities

2. The disclosure is objected to because of the following informalities:

(a) The ATCC address at page 56 is incorrect. The present address is: 10801 University Boulevard, Manassas, VA 20110-2209.

(b) The claims improperly use the sequence identifiers "SEQUENCE ID NOS" which should be "SEQ ID NOS:".

Appropriate correction is required.

### Rejections under 35 USC 112, second paragraph: Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 11-14, 33, 38 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) The claims fail to define the metes and bounds of the claimed invention, "polynucleotide...has at least 50% identity with...", because neither the claims nor the specification define any of the thousands of potential polynucleotides that meet the claim limitation. Furthermore, the specification fails to identify the algorithm and parameters therefor that define the claimed polynucleotide. Thus one of skill in the art would not be

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apprised of the scope of the claimed invention. It is suggested to recite defined polynucleotides in the claims.

(b) The claims further fail to define the claimed invention because "fragment" is not specifically defined in the claims or in the specification. The description at page 14 speaks in general terms of a nucleotide sequence having a variable number (6-20) of contiguous nucleotides and being "identical or complementary to, a region" of a particular polynucleotide. Neither the claims nor the specification define any of the thousands of potential "fragments" or "region" that meet this description. It is suggested to recite defined sequences.

(c) Claims 11-14 are indefinite because "capable of specifically hybridizing" is not understood in the context of the claims. It is unclear whether this is a method step or a property. It is suggested to change the phrase to --specifically hybridizes to--.

(d) Claim 33 is indefinite in being confusing over claim 11. The recitation "Composition of matter" does not distinguish the claims in scope or particularity because "composition of matter" merely identifies the statutory category of the claimed invention. It is suggested to cancel claim 33 or to distinguish it in some other way from claim 11.

**Rejections under 35 USC 102(b): Anticipation**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 11-14 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Hillier et al.. Polynucleotides having "at least 50% identity" with SEQ ID NOS:4, 5, 7 and 12 are disclosed by Hillier et al., the ESTs in applicant's reference numbers XP-002082617, XP-002082617, XP-002082618 and XP-002082620, respectively. The further limitations reciting how the polynucleotide is produced and the properties of "specifically hybridizing" and "encoding at least one BS200 epitope" are inherent in the reference polynucleotides.

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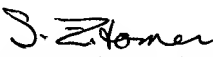
**Conclusion**

5. **No claim is allowed.** However, it is noted that SEQ ID NOS:15 and 16 are free of the prior art.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Zitomer whose telephone number is (703) 308-3985. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The official fax phone number for this Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
Stephanie W. Zitomer, Ph.D.

May 21, 1999

STEPHANIE W. ZITOMER  
PRIMARY EXAMINER